UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

HAARIN KWON, individually and on behalf of all others similarly situated, Plaintiff, v. NBTY, INC., UNITED STATES NUTRITION, INC., and HEALTHWATCHERS, INC., Defendants.	**DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS THE COMPLAINT** No.: 1:15-cv-03866-KAM-RML

Charles B. Casper
MONTGOMERY, McCRACKEN, WALKER & RHOADS, LLP
437 Madison Avenue, Floor 29
New York, NY 10022
Tel: (212) 867-9500
Fax: (212) 599-1759

William A. Delgado (admitted *pro hac vice*)
WILLENKEN WILSON LOH & DELGADO LLP
707 Wilshire Boulevard, Suite 3850
Los Angeles, CA 90017
Tel.: (213) 955-9240
Fax: (213) 955-9250

Attorneys for Defendants
NBTY, INC.,
UNITED STATES NUTRITION, INC. and
HEALTHWATCHERS, INC.

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I. INTRODUCTION

First, In his Opposition, Plaintiff makes a crucial concession: Plaintiff concedes that if the Complaint alleges that the Product label is misleading because the Product contains less "total" protein than stated, Plaintiff's claims are preempted. This is a crucial concession because that is the *only* reasonable interpretation of Plaintiff's allegations. (*See, e.g,* Complaint ¶ 4 ("By adding nitrogen-rich ingredients, Body Fortress appears to contain more protein than it actually does."); ¶ 35 ("Consumers are left with a product that contains less protein than represented, due to the presence of 'protein-spiking' ingredients.").) Therefore, all of Plaintiff's claims should be dismissed.

Second, Plaintiff's claims must be dismissed even if this Court accepts his argument that the Complaint alleges instead that the Product label's claim regarding protein content ("60 g PREMIUM PROTEIN") somehow falsely promises that the Product is "comprised solely of whey protein." (Opp., p. 10.) Such claims ***still*** would be preempted by Section 343-1(a) of the NLEA. Remedying such claims would require NBTY to differentiate between whey protein and protein from amino acids in labeling total protein content—a requirement "not identical to" that imposed by the FDA. It is, in fact, a requirement the FDA considered and rejected. *See* Food Labeling: Nutrient Content Claims, 58 Fed. Reg. 2302, 2344 (Jan. 6, 1993) (Cmt. 150).

Not only that, but Plaintiff's counter-argument is premised upon a false predicate: his assertion that the Product label "says it contains 60 grams of whey protein per two scoops." (Opp., p. 2.) But, as can be verified by simple reference to the label, that is not what the label states. It says: "60g PREMIUM PROTEIN." Neither Plaintiff's fictionalized version of the label, nor his reinterpretation of his allegations, can save his claims. His Complaint must be dismissed, whether the Court accepts his or NBTY's reading of the Complaint.

II. ARGUMENT

A. Plaintiff's Waiver Charge Is Baseless.

As an initial matter, Plaintiff mistakenly alleges NBTY "waived" any challenge to Plaintiff's GBL, negligent misrepresentation and fraud claims. To the contrary, NBTY plainly challenged each of those as preempted: "***Each of Plaintiff's causes of action under state common law and statutory law*** … is preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 343 *et seq*. ("FDCA"), as amended by the National Labeling and Education Act, 21 U.S.C. § 341, *et seq*. ("NLEA")." (Mot., p. 5 (emphasis added).)

B. Plaintiff Fails to Show His Claims Are Not Preempted.

1. Plaintiff Impliedly Concedes His Claims Are Preempted if His Complaint Is Given Its Plain Meaning.

Plaintiff's concession that total protein content claims are governed by the FDA must be taken as a concession that if his allegations are given their plain meaning—i.e., the label overstates the Product's "total" protein content—his claims are preempted.[1] Indeed, he readily admits the FDA regulates total protein content labeling and, concomitantly, calculation of protein content: "[T]he FDA requires that food products intended for human consumption state the amount of total protein contained in each serving size, 21 U.S.C. § 343(q)(1), and permits the manufacturer to calculate protein content "on the basis of the factor of 6.25 times the nitrogen content of the food." 21 C.F.R. § 101.9(c)(7). (Opp., p. 4.)

As this is the only reasonable reading of the Complaint, all claims should be dismissed. (*See, e.g*, Complaint ¶ 4 ("By adding nitrogen-rich ingredients, [the Product] appears to contain more protein than it actually does."); ¶ 9 ("Plaintiff Kwon … would not have purchased [the Product], or would have only paid for the protein actually delivered by [the Product], if he knew the truth about its protein content …."); ¶ 26 ("[The Product] also

[1] He urges his claims escape preemption because he does not complain about total protein content claims, but total "whey" content claims. (Opp., pp. 1-2.)

includes, for the purposes of 'protein-spiking,' (i.e., overstating the actual protein content) several free form amino acids, including, glycine, L-glutamine, and leucine."); ¶ 35 ("Consumers are left with a product that contains less protein than represented, due to the presence of 'protein-spiking' ingredients.").)

2. Plaintiff's Claims Are Preempted Even if This Court Accepts The Recasting of His Allegations.

To avoid preemption, Plaintiff now attempts to recast his allegations. Instead of relying on the allegations actually appearing in the Complaint (i.e., that the Product's total protein content is overstated), Plaintiff now argues the label would mislead a reasonable consumer to believe it contains "solely" whey protein (Opp., p. 7). Nevertheless, Plaintiff's claims still are preempted.

Plaintiff attempts to escape preemption by arguing that both 21 U.S.C. § 343(q)(1)(D) and 21 U.S.C. § 343(r)(1) are "inapplicable because the 'whey' label does not 'characterize[] the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2).' 21 U.S.C. § 343(r)(1)(A)" because "'whey' provides no indication of the 'total protein contained in each serving size,' 21 U.S.C. § 343(q)(1)(D)." (Opp., p. 8.) But Plaintiff sets up a straw man.

First, Plaintiff's argument is predicated upon Plaintiff's false assertion: the Product label "says it contains 60 grams of whey protein per two scoops." (Opp., p. 2.) But no such statement actually appears on the label, which states: "60g PREMIUM PROTEIN," and, "SCIENTIFICALLY DESIGNED WITH: PREMIUM WHEY PROTEIN[,] OVER 8 GRAMS OF BCAAs[,] CRYSTALLINE TAURINE[,]LEAN MASS ACTIVATORS."

Moreover, while 21 U.S.C. § 343(q)(1)(D) and 21 U.S.C. § 343(r)(1) do not govern representations regarding "whey," they do govern representations regarding protein. Here, Plaintiff challenges the claim, "60 g[rams] PREMIUM PROTEIN." Plaintiff cannot purport to mount a challenge to a label claim that plainly states the total amount of protein

and then argue that statutes governing claims regarding the total amount of protein have no application. Remedying Plaintiff's proposed claims would require NBTY to distinguish on the label which of the claimed 60 grams of total protein per serving comes from whey and which from amino acids. Where FDA and NLEA regulations permit NBTY to label protein content without such a distinction, Plaintiff's claims plainly would impose a "requirement for nutrition labeling of food that is not identical" to FDA requirements, and thus is preempted.[2] 21 U.S.C. §§ 343-1(a)(4)-(5).

Indeed, the plaintiff in *Gubala v. CVS Pharmacy, Inc.*, 2015 WL 3777627 (N.D. Ill. 2015) made nearly identical allegations ("Plaintiff primarily alleges that he was deceived by the use of the phrases 'Whey Protein Powder' and '26 grams of high-quality protein' on the product's front label into believing the 26 grams of protein were derived solely from whey protein"), and the Court held such claims were preempted for this reason: "Under Section 343–1(a)(1), the standard for labeling protein does not require CVS to distinguish between sources of protein …. Requiring CVS to differentiate between whey protein and protein from amino acids when labeling the protein content of its product would not be identical to the labeling requirements imposed by federal law." *Id*. at *4.

Plaintiff argues *Gubala* was "incorrectly decided," but, in fact, it is well-reasoned

[2] Plaintiff's brash assertion that the FDA has recognized that it is "misleading" to declare the protein content of a supplement that contains amino acids, is wholly unfounded. (Opp., p. 4 (citing Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements, 60 Fed. Reg. 67194-01).) The comment upon which Plaintiff relies refers to 21 C.F.R. § 101.36, which provides "Protein shall not be declared on labels of products that, other than ingredients added solely for technological reasons, contain *only* individual amino acids" (emphasis added). That regulation has no applicability here—and Plaintiff makes no contrary argument. Furthermore, as recently as 2014, the FDA revisited the standard for calculating protein to consider whether "better, analytical methods" exist, and yet the regulations still provide "[p]rotein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food ….'" Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 79 Fed. Reg. 11880-01; 21 C.F.R. § 101.9(c)(7).

and supported by a critical fact, which Plaintiff ignores: the FDA considered and rejected as "'not necessary'" the very sort of "source" labeling requirements Plaintiff's claims would impose. *See id.* (quoting Food Labeling: Nutrient Content Claims, 58 Fed. Reg. 2302, 2344 (Jan. 6, 1993) (Cmt. 150)).

Plaintiff additionally argues 21 U.S.C. § 343(q)(1)(D) does not govern here because it governs only the "'Supplemental Facts' section located on the back of the [Product] label," whereas he challenges only claims made on the front. (Opp., p. 8.) This argument, —that his allegations should be read to challenge the claim of 60 grams of protein per serving on the label front, but not the identical claim on the back, makes no sense. Certainly if Plaintiff prevailed in his claims, and the protein content claims on the label front were required to be changed, the claims on the back would have to be changed as well—thus imposing requirements different than Section 343(q)(1)(D), and compelling the conclusion that Plaintiff's claims are preempted.

Furthermore, because FDA and NLEA regulations permit NBTY to state that the Product contains 60 grams of protein per serving in the "Supplemental Facts" panel, ***the same claim elsewhere on the label cannot be considered "misleading."*** *See Chacanaca v. Quaker Oats Co*., 752 F. Supp. 2d 1111, 1119-21 (N.D. Cal. 2010) ("Plaintiffs argue that their state law claim asserts only that, removed from the nutrition box, the 0 grams trans fat statement is misleading because it implies that Chewy Bars contain no trans fats whatsoever (as opposed to the '0 gram' that appears in the nutrition box, which means instead anywhere from none to 'nutritionally insignificant amounts' of trans fat, not exceeding 0.5 gram per serving) … [I]f 'nutritionally insignificant amounts' of less than 0.5 gram trans fats means the same thing, according to Agency regulations, as '0 grams,' then the use of the latter language in an express nutrient content claim would not be misleading within the meaning of section (r) or any of its regulations.… [T]he plaintiffs'

state law claims therefore seek to impose a non-identical burden. It is for this reason that plaintiffs' claims relying on the use of this particular statement are preempted."). Indeed, the FDA has "expressed a preference for internal consistency between the nutrition box and the rest of the label," in order "to prevent consumer confusion …." *See id.* at 1121.

In sum, contorting his allegations to make this case about "total whey" rather than "total protein" does nothing to save Plaintiff's claims from preemption.

3. No Other Court Has Allowed Such Claims to Go Forward.

Plaintiff relies on *Bruaner v. MusclePharm Corp.*, 2015 WL 4747941 (C.D. Cal. Aug. 11, 2015) and *Clay v. Cytosport, Inc.*, 2015 WL 5007884 (S.D. Cal. Aug. 19, 2015) in arguing against preemption, but their facts bear no resemblance to those here.

In *Bruaner*, the Court held plaintiff's claims were not preempted where he alleged "defendant falsely 'claim[s] … [its] product … do[es] not count non-protein, nitrogen sources towards [its] protein content,'" but, in fact, the product did. *Bruaner*, 2015 WL 4747941, at *7. The *Bruaner* Court specifically distinguished these allegations from those in *Mee* and *Gubala*—which resolved cases almost identical to this one:

> In *Gubala v. CVS Pharmacy, Inc.*, 2015 WL 3777627 (N.D. Ill. 2015), and *Mee v. I A Nutrition, Inc.*, 2015 WL 2251303 (N.D. Cal. 2015), plaintiffs alleged that the amount of protein … was overstated because they included non-protein nitrogen-containing ingredients in their calculations. In *Gubala*, the plaintiff asserted that he was "deceived by the use of the phrases 'Whey Protein Powder' and '26 grams of high-quality protein' on the product's front label into believing the 26 grams of protein were derived solely from whey protein." [Cite] The court found, however, that "[r]emedying the allegedly deceptive labeling would require CVS to…identify each source of protein …. Requiring CVS to differentiate between whey protein and protein from amino acids when labeling the protein content of its product would not be identical to the labeling requirements imposed by federal law." *Id.*
>
> Similarly, in *Mee*, plaintiff alleged that "calculating protein content using nitrogen as a 'tag,' i.e., the method allowed under [FDA regulations], does not result in a direct measure of the actual protein content … [Cite] The court found that the claim was preempted because "it [sought] to base liability on defendant's failure to employ a testing procedure not imposed by or contained in any federal regulation, and, indeed, is a challenge to the very method allowed by the FDA." *Id.*

Id. at *8. The Court explained Bruaner's allegations were different because "remedying the alleged violations would not 'require [defendant] to specifically identify each source of protein … [cite], nor … require 'a testing procedure not imposed by or contained in any federal regulation[.]' [cite]." *Id.* Rather, "remedying the violation would merely mean that defendant could no longer make untrue statements such as 'we don't include amino acids, creatine[,] and other non-protein, nitrogen sources in our protein content.'" *Id.* Here, Plaintiff's allegations are like those in *Gubala* and *Mee*, not *Bruaner*, and thus, in keeping with each *Bruaner*, *Gubala*, and *Mee*, Plaintiff's claims are preempted.

Clay is likewise unavailing. In *Clay*, the plaintiff alleged, based upon testing, "Defendant provides less protein than that advertised on its Muscle Milk RTD Products' labels." *Clay*, 2015 WL 5007884, at *2. Defendant argued the claim was preempted because the plaintiff did not allege his testing "complie[d] with … [21 CFR §] 101.9(c)(7)," ("[p]rotein content may be calculated on the basis of the factor of ***6.25 times the nitrogen content of the food*** ….'"). *Id.*; 21 C.F.R. § 101.9(c)(7) (emphasis added). The Court rejected the preemption argument because, at the pleading stage, it was not clear that plaintiff sought to impose a requirement other than 21 C.F.R. § 101.9(c)(7):

> ***While the Court agrees with Defendant that this is the standard that the FDA holds Defendant to***, the Court finds that Plaintiffs['] allegations are sufficient at this point in the proceedings.… Defendant challenges the allegations because they do not identify the type of testing … employed. This argument is not appropriate for a motion to dismiss. ***Of course, in order to ultimately prevail on these claims, Plaintiffs will have to prove that Defendant did not comply with the FDCA provisions listed above.*** However, to state a claim, Plaintiffs only need to allege a plausible violation of the FDCA.

Id., at *4 (emphasis added). In other words, the Court in *Clay* permitted the claim to go forward because it was plausibly alleged that the subject product did not contain the amount of protein advertised—which the Court recognized could only be ultimately proven by showing that, when the product was tested in conformity with 21 C.F.R. §

101.9(c)(7), it did not contain the amount of protein claimed.

Here, Plaintiff's allegations cannot plausibly be construed to allege the Product label violates the FDCA by overstating protein content calculated in conformity with 21 C.F.R. § 101.9(c)(7) ("calculated on the basis of the factor of 6.25 times the nitrogen content of the food"). To the contrary, Plaintiff alleges the label overstates the protein content ***because*** it is calculated in conformity with 21 C.F.R. § 101.9(c)(7): "Nitrogen is the 'marker' used by the common test as a rough estimate of the amount of protein in a product, but it is not a direct measurement of the actual protein content. By adding nitrogen-rich ingredients, Body Fortress appears to contain more protein than it actually does." (Complaint ¶ 4.) In short, *Clay* likewise supports preemption here.

C. Privity Is Required to State a Breach of Implied Warranty Claim Here.

Plaintiff argues his implied warranty claim survives because the required privity element "is not required for breach of implied warranty claims concerning sealed food products." (Opp. p. 17.) He is wrong. *See Weisblum v. Prophase Labs, Inc.*, 88 F. Supp. 3d 283 (S.D.N.Y. 2015) ("Plaintiffs … cite several cases holding … privity is not required with regard to implied warranty claims 'concerning sealed food products or medicines.' Those cases, however, 'preceded the enactment of the UCC, which displaced [them].' [Cite.] Accordingly, Plaintiff's claims … for breach of implied warranty are dismissed.").

D. The "Express Warranty" Plaintiff Purports to Identify Does Not Exist; Plaintiff Fails to Rebut that "Premium" is Puffery.

Plaintiff asks this Court to read the statement "60 g[rams] PREMIUM PROTEIN" as an ***express warranty*** that the product contains "60 g[rams] whey protein." (Opp., p. 15.) But that's not what the label says. And for that simple reason, it certainly cannot be what the label expressly warrants. Nor would such a reading make sense. The label states it is "designed ***with***" whey protein—it doesn't say it is "designed ***of***" whey protein. Nor does it suggest other ingredients are not included—to the contrary, other key ingredients are

touted on the front label. In short, where the "express warranty" Plaintiff purports to identify does not exist, Plaintiff cannot state a claim for breach of express warranty.

Additionally, to the extent Plaintiff argues "premium" is not mere puffery, he fails to cite to a single case suggesting otherwise, or to adequately distinguish the cases cited by NBTY holding to the contrary. Plaintiff's attempted distinction of *Gubala's* holding that the similar claim "high quality protein" was mere puffing is a premised upon an assertion made of whole cloth ("Defendants themselves define 'PREMIUM WHEY PROTEIN' to mean 'PREMIUM PROTEIN'") (Opp., p. 16), and should be disregarded. *Gubala* is directly on point, well-reasoned, and compels the conclusion that Plaintiff cannot state a claim for breach of express warranty. *See Gubala*, 2015 WL 3777627, at *7 ("Plaintiffs [sic] breach of express warranty claim 'that the Product "contained 26 Grams of high quality protein per serving,'" as plead, fails … as 'puffing,'….'") (citations omitted).

E. Plaintiff's Claim for Violation of the Magnuson-Moss Warranty Act Fails.

For the reasons set forth in Section B, *supra*, the FDCA most certainly governs Plaintiff's claims, and thus his MMWA claim must be dismissed because the MMWA is "inapplicable" to warranties otherwise governed by Federal law. 15 U.S.C. § 2311(d).

Furthermore, Plaintiff's claim for violation of the MMWA should be dismissed because, as with Plaintiff's express warranty claim, Plaintiff asks this Court to permit him to state a claim based upon a nonexistent statement. That is, Plaintiff urges this Court to construe the label to state, "60 g[rams] of PREMIUM [WHEY] PROTEIN," even though that phrase appears nowhere on the label. (Opp., p. 19.) By definition, that cannot be an "express warranty"—not under New York common law, and not under the MMWA, and his warranty claims must be dismissed for this straightforward reason.

Additionally, Plaintiff concedes he has failed to allege a claim that the Product is "defect free" within the meaning of the MMWA. (Opp., p. 20.) And he otherwise fails to

state a claim that the Product promises a "specified level of performance over a specified period of time," such that he alleges a "warranty" within the meaning of the MMWA. The very cases Plaintiff cites underscore that the label claims here bear no resemblance to such warranties. *See, e.g., Brady v. Basic Research, L.L.C.*, 2015 WL 1542094, *11 (E.D.N.Y. Mar. 31, 2015) (MMWA claim premised on promise of "'456% More Weight Loss Than America's # 1 selling Ephedra–Based Diet Pill,' in 'a little over 6 weeks.'"). Plaintiff fails in his attempt to distinguish the authorities upon which NBTY relies on the grounds that "they turned on the plaintiffs' failure to allege a 'specific period of time,' whereas here, Plaintiff specifically pleads … [the Product's] expiration date." (Opp., p. 21.) To the contrary, Plaintiff ignores the directly on-point holding in *Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371 (S.D.N.Y. 2014): "If the existence of a 'Best Buy' date were enough to transform all labels into warranties, virtually any grievance about a consumer product—food or drug—would be actionable under the MMWA. That is not how the statute was meant to work." *Id.* at 378 (dismissing MMWA claim premised upon a "best buy" date).

F. Rule 8 Does Not Save Plaintiff's Unjust Enrichment Claim From Dismissal.

Plaintiff identifies no allegations supporting his unjust enrichment claim other than those underlying his false advertising claims; thus, his duplicative claim must be dismissed—along with his argument that Rule 8 indulges such a claim. *See Goldemberg v. Johnson & Johnson Consumer Co., Inc.*, 8 F. Supp. 3d 467, 483 (S.D.N.Y. 2014) (rejecting identical Rule 8 alternative pleading argument, noting: "[I]f in New York courts the … claim for unjust enrichment would be unavailable—as here, where Plaintiff simply restates elements of other claims—it must equally be unavailable in the Federal courts").

IV. CONCLUSION

For the reasons set forth above and in the moving papers, pursuant to Federal Rule of Civil Procedure 12(b)(6), the Complaint should be dismissed without leave to amend.

Dated: October 2, 2015

MONTGOMERY, McCRACKEN,
WALKER & RHOADS, LLP

By: */s/ Charles B. Casper*
Charles B. Casper
437 Madison Avenue, Floor 29
New York, NY 10022
Tel: (212) 867-9500
Fax: (212) 599-1759
E-mail: ccasper@mmwr.com

-and-

WILLENKEN WILSON LOH &
DELGADO LLP

By: */s/ William A. Delgado*
William A. Delgado (adm. *pro hac vice)*
707 Wilshire Boulevard, Suite 3850
Los Angeles, CA 90017
Tel.: (213) 955-9240
Fax: (213) 955-9250
E-mail: wdelgado@willenken.com

Attorneys for Defendants
NBTY, INC., UNITED STATES
NUTRITION, INC. and
HEALTHWATCHERS, INC.